

REMARKS

Claims 1-14 are pending in the current application.

Claims 1-3, and 5 have been amended. Support for the amendment to claims 1 and 3 is located at least in paragraph 9 of the instant application. Claim 2 was amended to include a period at the end of the claim. Claim 5 has been amended to clarify the claim language. Support for the amendment to claim 5 is located at least in page 6, lines 6-10, where it is stated “the cover elements 5 comprise a material that is softer than that of the cap portion 2 and irreversibly deforms, at least at an edge region engaging in the annular groove associated with the cover element 5, when a cover element 5 is pulled off from the cap portion, so that after the cover element has been pulled off the cap portion 2 it cannot be re-inserted in the annular groove.” See also paragraph 15 which states that “the cover element is permanently deformed in the region of the undercut as it is pulled away and removed from the cap portion.” The underlined portions make it clear that the edge has been removed along with the cover element and therefore the edge is still secured to or attached to the cover element and one of ordinary skill in the art would understand this to be so. Accordingly, no new matter has been added by way of this amendment. Entry of this Amendment is respectfully requested.

Restriction Requirement

The Examiner has required restriction of claims into 2 groups: claims 1-4, which are drawn to a process for producing a closure for a medicine bottle and claims 5-14, which are drawn to a closure for a medicine bottle. The Examiner argues that the two groups of claims are related as process of making and process made and that they are distinct because the cover material (5) could be placed in the groove surrounding the opening, and/or the sealing layer (4) could be placed in the cap (2), instead of by injection molding process without material bonding.

Applicants respectfully traverse the Restriction Requirement for the following reasons. The assumption of the Examiner that it would be possible to use another method of injection molding is not realistic because it is through the injection process that the edge of the cover is able to be placed inside of the annular groove and it is also how the cover is able to achieve sterile contact with the elastic puncturable sealing layer. Further, because of the shape of the edge portion it is not viable to insert the edge in the groove manually as it would permanently deform

the edge. Accordingly, it is respectfully requested that the Examiner withdraw the Restriction Requirement.

In the event the Examiner maintains the election requirement, Applicant hereby affirms the election of the invention of Group II, claims 5-14.

Rejection Under 35 U.S.C. § 112

The Examiner has rejected claim 12 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. The Examiner argues that it is unclear how claim 12 can limit the sealing layer being welded flush to the cap portion when claim 5 states that the sealing layer makes contact “free from any material bond.” Applicants respectfully traverse the rejection and the argument in support thereof.

The statements “with no material bond” and “free from any material bond” in claim 5 pertain to the following items, respectively:

1. the cover element (5) is interlockingly connected to the rim (8)
and
2. sealing layer (4) makes flush, sterile contact ... with a reverse side of the cover element (5) facing the opening (3).

Claim 12, on the other hand, refers the sealing layer (4) being welded flush to the cap portion (2). (See Fig. 2) Since the sealing layer (4) can contact the cover element (5) free from any material bonds and simultaneously, the sealing layer (4) can be welded flush to the cap portion (2), claim 12 is not indefinite. Accordingly, it is respectfully requested that the rejection be reconsidered and withdrawn.

Rejections Under 35 U.S.C. § 103(a)

The Examiner has rejected claims 5-12 under 35 U.S.C. § 103 (a) as being unpatentable over U.S. Patent No. 4,501,372 to Hansen (“Hansen”) in view of U.S. Patent No. 4,407,424 to Heyn (“Heyn”). The Examiner argues that Hansen teaches a tear-open closure for a container that has a cap portion with at least one opening and an elastic, puncturable sealing layer covered by a cover element. The Examiner acknowledges that Hansen fails to teach the cover releasably connected to the container by an interlock encircling the opening. Turning to Heyn, the

Examiner contends that Heyn teaches a means for securing a cover to a container opening that has a pull-plug interlocked into a container groove encircling the opening. The Examiner concludes that it would have been obvious to one having ordinary skill in the art to modify the closure of Hansen with the frangible removable panels disclosed in Heyn.

Regarding claim 10, the Examiner states that the closure arrangement of Heyn requires the closure tab to be formed of plastic, while the can end is formed of metal, which facilitates the cutting of the plastic closure upon removal. The Examiner concludes that it would therefore be obvious to form the closures of Hansen of a material softer than those of the cap in order to promote fracture of the closures upon removal. Applicants strenuously, but respectfully traverse the rejection and the arguments in support thereof.

First of all, Hansen and Heyn are improperly combined. Hansen is directed to a medical container where sterility is at a heightened state because frequently the contents are injected into the skin. Whereas Heyn is directed to a beverage container, which does not require the same level of sterilization because the contents are consumed orally. One skilled in the art would not look to the beverage container industry for ideas on how to maintain a sterile environment in a complex closure such as in Hansen.

Hansen and Heyn do not disclose or suggest, either alone or in combination, the present invention. Claim 5 recites, *inter alia*, that the edge region 6 remains integral with the cover element 5 upon removal of the cover element 5. Hansen teaches a cap with two tear-open closures that are opened by pulling a ring 9, 10. Heyn is directed to a metal can with a plastic closure that is designed to tear upon opening (*See*, col. 1, lines 28-30 and Fig. 7). Both Hansen and Heyn are directed to closures that tear upon opening unlike the present invention. The present invention offers an advantage of not tearing upon opening the container. When containers have closures that require tearing – the risk of having particulate matter from the tearing occurs. This can lead to contamination, which is not advantageous to maintaining a sterile container. Neither Hansen nor Heyn disclose or suggest the present invention's cover element 5 where the edge region 6 remains integrated with the cover element 5 upon removal of the cover element. In the present invention separation occurs by deformation and disengagement of the interlocking interaction between the cover element 5 and the cap portion 2. The edge region remains integral with the cover element. The present invention reduces the risk of contaminating the product with particulate or debris that can occur from removing the circular

portion as disclosed in Hansen, because the cover element 5 and associated edge 6 of the present invention is a separate piece unto itself, which remains integral after separation which reduces the risk of particulate matter being generated from the opening of the container.

Even if the combination were proper, the modified Hansen closure would still not disclose each and every element of claim 5. If the weakened area of Hansen was replaced with the tear away closure of Heyn, the modified Hansen closure would not include an edge region that remains integral with the cover element upon removal of the same. In Heyn a portion of the cover element is retained by the container (see Fig. 7) and it is therefore not integral with the closure upon removal of the same.

Claims 6-12, are dependent upon claim 5, which is allowable, based on the above arguments, either directly or indirectly and therefore, are also allowable.

Accordingly, Heyn does not make up for the deficiencies of Hansen. Therefore, claims 5-12 are not obvious over Hansen in view of Heyn.

The Examiner has rejected claims 13 and 14 under 35 U.S.C. § 103 (a) as being unpatentable over Hansen in view of Heyn and further in view of U.S. Patent No. 4,746,017 to Howard ("Howard"). The Examiner acknowledges that Hansen does not teach the gripping tabs extending at right angles and centrally located. The Examiner contends that Howard teaches a removable cover disk with a tab extending vertically and centrally from the disk, for removal of the disk portion. The Examiner concludes that it would have been obvious to modify the closure gripping tabs of Hansen, providing the centrally located and vertically extending tab taught by Howard, motivated by the benefit of providing an equivalent means of allowing a user to remove the closure to expose the pierceable sealing layer. The applicants respectfully traverse the rejection and the arguments in support thereof.

The above arguments pertaining to claims 5-12 regarding Hansen and Heyn are equally applicable to this rejection. Howard and Heyn clearly do not make up for the deficiencies of Hansen. The closure of Howard is directed to a bottle with an opening that has a frangible sealing disk 28 that is removed from an aperture 26 by tab 29. The cover element 5 and associated edge 6 of the present invention is releasably attached. The present invention does not require tearing or breaking of the cover in order for it to be removed.

Additionally, claims 13 and 14 are dependent on claims 5, either directly or indirectly, and claim 5 is allowable over the cited prior art according the arguments and amendment above.

CONCLUSION

Accordingly, the claims of the present invention are allowable in view of the remarks and arguments above. Reconsideration and withdrawal of the rejections is respectfully requested.

Respectfully submitted,

Bernrd Becker

Aug 15, 2005
(Date)

By: Colleen R. Butcher

COLLEEN R. BUTCHER

Registration No. 56,315

AKIN GUMP STRAUSS HAUER & FELD LLP

One Commerce Square

2005 Market Street, Suite 2200

Philadelphia, PA 19103-7013

Telephone: 215-965-1200

Direct Dial: 215-965-1372

Facsimile: 215-965-1210

E-Mail: cbutcher@akingump.com

MGB/CRB:cmb
7438988